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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,762	06/07/2006	Albertha Walhout	07917-232US1 UMMC 03-137	1626
26161 7590 08/27/2010 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			NOTIFICATION DATE 08/27/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/561,762	Applicant(s) WALHOUT ET AL.	
	Examiner Michele K. Joike	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed June 11, 2010. Claims 1-17 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed December 11, 2009 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 11, 12 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al in view of Fields et al and in further view of Sugawara et al.

Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of Luo et al.

Art Unit: 1636

Claims 9 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of Chalfie et al.

Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of Cost et al.

Claims 15 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of US 5,965,368.

Claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of US 5,525,490.

These rejections are maintained for reasons for record, as well as for the reasons stated below.

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicant's arguments filed June 11, 2010, have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Walhout et al. does not teach or suggest that the vector can be integrated into the genome of a yeast or mammalian cell. The vector contains sites for integration into and from E. coli. Furthermore, the integration reactions require elements not naturally

Art Unit: 1636

present in yeast or mammalian cells, including the attB site, Int and IHF. The ORFs are never integrated into an organism, and there is no inherent disclosure of integration of a bait element into a yeast or mammalian cell.

The only protein Fields et al teach that contains both a DBD and TAD is GAL4. The disclosed fusion proteins have either a DBD or TAD. Fields does not teach the detection of DNA-protein interactions. Walhout et al. discloses the preparation of a vector with an ORF fused to a binding domain for detection of protein-protein interactions (two-hybrid), rather than DNA-protein interactions. It would not have been obvious to substitute the ORF of Walhout et al. with the UAS_G disclosed in Fields et al. because the regions involved are used for divergent purposes. Additionally, because of the differences in function, the sizes of the ORFs disclosed in Walhout et al. cannot be used to meet the size limitation of the claimed bait element. The Office has provided no teaching or suggestion of a bait element of at least 250 base pairs.

Sugawara et al. does not teach or suggest a bait element having at least 250 base pairs as presently claimed. Further, Sugawara et al. fails to disclose or suggest the use of lambda recombination sites. And the ORFs disclosed in Walhout are not functionally equivalent to the bait element recited in the claims.

Luo et al., Chalfie et al and Cost et al do not teach or suggest the detection of DNA-protein interactions, a cell with a bait-reporter construct integrated into its genome, or a bait element flanked by lambda recombination sites.

The '368 and '490 patents do not teach or suggest a cell whose genome includes one or more integrated bait-reporter constructs, wherein each of the one or more bait-reporter constructs includes (a) a single copy of a bait element having at least 250 base pairs flanked by lambda recombination sites, wherein the bait element comprises at least 250 base pairs and (b) a reporter gene.

Applicant's arguments have not been found persuasive for the following reasons.

The vectors taught by Walhout et al can be integrated into the genome (p. 579). Figure 2 teaches integration into the E. coli genome. While the reference does not explicitly state the vectors are integrated into a yeast genome, it is inherent that they are. Vectors with lambda recombination sites are transformed and integrated into E coli. It follows that vectors with lambda recombination sites that are transformed into yeast will also integrate. Walhout et al teach on page 579 that the integration reaction requires Int and IHF. One of skill in the art would know that if they want to integrate a vector into the yeast genome, that these enzymes would also be required in the yeast cell. The purpose of flanking the ORF with the lambda recombination sites is for integration into a genome. Walhout et al also teach in figure 2 that many different destination vectors can be made for use in yeast two hybrids and in mammalian cells, as well as other systems. In other words, this recombinational cloning method using the lambda system can be expanded to include other systems and organisms.

Fields et al teach use of a bait element as defined by the specification. The bait element does not have to be a promoter sequence. Paragraph 12 of the instant

Art Unit: 1636

specification states that “[t]he new system can be used to screen any DNA sequences ("bait elements"), including promoters from species from *C. elegans* to *Homo sapiens*, to identify associated DNA-binding proteins and transcription factors.” In claim 1, the bait element and activation domain are in separate constructs. Fields et al teach assessing activation of a reporter gene when the fusion protein of a DBD and TAD bind to the binding element (UAS_G). See figure 1. Walhout et al also teach separate constructs, one of which is a bait element flanked by att sites. The construct can also include a marker gene. Fields et al teach binding of a DNA sequence and an assessment of reporter activation. The sequences in Walhout and Fields do not have different functions. In both cases, they contain elements that will accept binding of a protein, which then will activate reporter/marker expression.

As for Sugawara et al, Chalfie et al, Luo et al and Cost et al, Walhout et al and Fields et al combined teach a bait element having at least 250 base pairs, the detection of DNA-protein interactions, a cell with a bait-reporter construct integrated into its genome, or a bait element flanked by lambda recombination sites. As noted above, there are no deficiencies to cure.

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1636

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/
Primary Examiner, Art Unit 1636

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